

Message Text

PAGE 01 STATE 026127
ORIGIN HEW-06

INFO OCT-01 ISO-00 IO-13 AF-08 ARA-10 EA-09 EUR-12 NEA-10
OES-06 MED-03 /078 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP:JFRY
DHEW/OIH: BROYSTER
NEA/EX:EGABI;GTON(INFO)
ARA/EX:CJACOBINI(INFO)
EA/EX:JRCUNNINGHAM(INFO)
EUR/EX:JLTULL(INFO)
AF/EX:JTIERNEY(INFO)

-----050211Z 065829 /70

P 042252Z PEB 77
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E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, XX

SUBJECT: DEFECTIVE OXYGENATOR SUPPORT CLAMP ASSEMBLY
(RECALL T-029-7)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: HARVEY MODEL H-300 OXYGENATOR SUPPORT CLAMP ASSEMBLY. THE CLAMP ASSEMBLIES ARE USED TO HOLD SINGLE USE BLOOD OXYGENATOR DURING HEART-LUNG SURGERY. THE HARVEY H-300 CLAMP ASSEMBLY/OXYGENERATOR SYSTEM IS CONNECTED TO A MAST BY THE UPPER MAST SCREW CLAMP. THUS THE CLAMP ASSEMBLY/OXYGENATOR CAN BE POSITIONED AT VARYING HEIGHTS AS APPLICABLE DURING THE SURGICAL PROCEDURE. THE BLOOD OXYGENATORS ARE HELD BY THE H-300 SUPPORT CLAMP AS FOLLOWS:
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THE BOTTOM OF THE SUPPORT CLAMP HAS A SQUARE POST WHICH INSERTS INTO THE BOTTOM OF THE OXYGENATOR. THE TOP OF THE OXYGENATOR IS HELD BY A SPRING-PLUNGER, WHICH FITS OVER A TOP NUB OF THE OXYGENATOR.

PRODUCT IDENTIFICATION: A STICKER LABEL ON THE UPPER SUPPORT IS LABELED "HARVEY MODEL H-300, WILLIAM HARVEY RES-

EARCH CORPORATION, SANTA ANA, CALIFORNIA 92705". THE CLAMP IS PACKED IN A CLEAR PLASTIC TIE SEAL BAG AND IS THEN PUT INTO A PLAIN UNLABELED BOX. VERSIONS 1-3 OF THE CLAMP ASSEMBLY CONSISTS OF THREE PIECES, AN UPPER AND LOWER SUPPORT (OR BRACKET) OF WHITE ALUMINUM AND A SUPPORT MAST OF BLACK METAL. VERSION NUMBER 4 IS A ONE PIECE STAINLESS STEEL UNIT WITH BLACK SUPPORT (OR BRACKETS). THERE ARE NO LOT OR SERIAL NUMBERS USED.

MANUFACTURING FIRM: THE DEVICE IS CUSTOM MANUFACTURED BY COLUMBIA SCREW PRODUCTS INC., 2901 SOUTH HALLADAY, SANTA ANA, CALIFORNIA 92705 FOR WILLIAM HARVEY RESEARCH CORPORATION.

DISTRIBUTOR AND RECALLING FIRM:

WILLIAM HARVEY RESEARCH CORPORATION
1940 EAST OCCIDENTAL STREET
SANTA ANA, CALIFORNIA 92705

2. REASON FOR RECALL:

THE FAILURE OF THE DEVICE TO SUPPORT THE OXYGENATOR DURING OPERATION AND UNDER NORMAL CONDITIONS OF ITS INTENDED USE MAY RESULT IN SITUATIONS PRESENTING AN IMMEDIATE HAZARD OF A LIFE THREATENING NATURE TO PATIENTS REQUIRING ITS USE DURING HEART-LUNG SURGERY. THERE WERE TWO COMPLAINTS OF DEATH ASSOCIATED WITH THE SUPPORT CLAMP
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ASSEMBLY MALFUNCTION.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED PRODUCT NOTIFICATION LETTER DATED 15 DECEMBER 1976 EXPLAINING IN DETAIL THE PROBLEMS ASSOCIATED WITH ALL FOUR VERSIONS OF THE MODEL H-300 OXYGENATOR SUPPORT CLAMP ASSEMBLIES WHICH WERE MARKETED FROM NOVEMBER 1972 THRU DECEMBER 1976. THE SUPPORT CLAMPS ARE NOT, REPEAT NOT, BEING PHYSICALLY RECALLED FROM THE CONSIGNEES. QUESTIONS RE RECALL SHOULD BE REFERRED TO FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:

QUEEN PAHLAVI FOUNDATION
CARDIOVASCULAR RESEARCH
TEHRAN, IRAN

MR. SERGIO ZARELLI ETABLISSEMENTS PAUL LOUIS
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<< END OF DOCUMENT >>

Message Attributes

Automatic Decaptioning: X
Capture Date: 22-Sep-1999 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: EQUIPMENT, MEDICAL CARE, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 04-Feb-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Document Unique ID: 00
Drafter: DHEW/FDA: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: n/a
Expiration:
Film Number: D770041-0834
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t197702100/baaaavey.tel
Line Count: 352
Litigation Code IDs:
Litigation Codes:
Litigation History:
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Message ID: ee4b1fbf-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 7
Previous Channel Indicators:
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 10-Nov-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3233377
Secure: OPEN
Status: <DBA CORRECTED> jms 970904
Subject: DEFECTIVE OXYGENATOR SUPPORT CLAMP ASSEMBLY (RECALL T-029-7)
TAGS: ETRD, OGEN, TBIO, US, XX
To: ROME BERN MULTIPLE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/ee4b1fbf-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
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22 May 2009
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